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#### 4. Program Regulations

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#### 442.401: Introduction

130 CMR 442.000 states the requirements and procedures for the purchase and repair of orthotics covered under MassHealth. All providers of orthotics participating in MassHealth must comply with MassHealth regulations, including, but not limited to, regulations set forth in 130 CMR 442.000 and in 130 CMR 450.000: *Administrative and Billing Regulations* and 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices*.

#### 442.402: Definitions

The following terms used in 130 CMR 442.000 have the meanings given in 130 CMR 442.402 unless the context clearly requires a different meaning. Conditions of coverage and payment for services defined in 130 CMR 442.000 are not determined by these definitions, but by application of regulations elsewhere in 130 CMR 442.000 and in 130 CMR 450.000: *Administrative and Billing Regulations*.

Adjusted Acquisition Cost — except where the manufacturer is the provider, the price paid by the provider to the manufacturer or any other supplier for orthotic or pedorthic devices, customized equipment, or supplies, excluding all associated costs such as shipping, handling, and insurance costs in accordance with 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices*. As provided in 101 CMR 334.00, where the manufacturer is the provider, the adjusted acquisition cost cannot exceed the actual cost of the raw materials.

American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC) — a national certifying and accrediting body for the orthotic, prosthetic and pedorthic professions, recognized as a deemed authority for facility accreditation by CMS.

American Standard Last Sizing Schedule — the numerical shoe sizing system used for shoes in the United States.

Board of Certification/Accreditation International (BOC) — BOC is an independent certifying and accrediting body for practitioners and suppliers of comprehensive orthotic and prosthetic care, and is recognized as a deemed authority for facility accreditation by CMS.

Centers for Medicare and Medicaid Services (CMS) — a federal agency responsible for administering the Medicaid and Medicare programs created under the authority of Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), and Title XVIII of the Social Security Act (42 U.S.C. 1395-1395pp).

Consignment Closet — an arrangement in which an orthotics provider maintains inventory at a prescribing provider's location, which is not the orthotics provider's service facility, for delivery to members on behalf of the orthotics provider.

Custom-fabricated — an orthotic made for a specific patient from his/her individual measurements and/or pattern.

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Custom-fitted/prefabricated — a prefabricated device or product that has been manufactured from standard molds or patterns and that requires substantial modification for fitting from an ABC- or BOC-certified orthotist or an individual who has equivalent specialized training.

Custom-molded Shoe — an individually patterned shoe fabricated to meet the specific needs of an individual. A custom-molded shoe is not off-the-shelf, stock, or prefabricated. The shoe is individually constructed by a molded process over a modified positive model of the individual's foot. It is made of leather or other suitable material of equal quality, has removable customized inserts that can be replaced if necessary according to the individual's condition, and has some form of shoe closure.

Date of Service — the date of service as specified in 130 CMR 442.424, as applicable, for delivery of the final orthotic product or service to the member, or as specified in 130 CMR 442.406(D), consistent with 130 CMR 450.231: *General Conditions of Payment*, for custom fabricated items ordered but not furnished to a member.

Detailed Written Order — the written prescription and statement of medical necessity justification for the specified orthotic services from the member's prescribing provider that meets the requirements at 130 CMR 442.409.

EOHHS — the Executive Office of Health and Human Services established under M.G.L. c. 6A.

Fitter of Therapeutic Shoes for Diabetics — an individual who is educated and trained in the provision of non-custom therapeutic shoes for diabetics and non -custom multi-density inserts including patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

Foot Deformity — a deformity of the foot that may be congenital or acquired, where the foot is no longer in normal anatomical position, proportion or alignment.

Healthcare Common Procedure Coding System (HCPCS) — for purposes of 130 CMR 442.000, HCPCS refers to the Level II HCPCS codes which are maintained by CMS, adopted by the MassHealth agency and used by providers to bill for certain medical services, devices, and supplies, including all orthotic services.

Home — for the purposes of the provision of orthotics, a member's home may be a dwelling owned or rented by the member, relative's or other person's home in which the member resides, a rest home, assisted living, or another type of group residence in a community setting in which normal life activities take place. A home does not include an institutional setting including but not limited to, a hospital, nursing facility or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board, except for items that are allowable pursuant to 130 CMR 442.410.

Hospital — a facility that is licensed or operated as a hospital by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health that provides diagnosis and treatment on an inpatient or outpatient basis for patients who have any of a variety of medical conditions.

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**Initial Order** — a written, electronically submitted or documented verbal communication from the member’s prescribing provider to the provider of orthotics to assess and evaluate the member for the specified orthotic service, and which meets the requirements of 130 CMR 442.409.

**Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID)** — a facility, or distinct part of a facility, that provides intermediate care facility services as defined under 42 CFR 440.150, and that meets Federal conditions of participation, and is licensed by the State primarily for the diagnosis, treatment, or rehabilitation for individuals with intellectual disabilities; and provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration for health or rehabilitative services to help individuals function at their greatest ability.

**Last** — a model that approximates the shape and size of the foot and over which a shoe is made. A last is usually made of wood, plastic, or plaster.

**MassHealth** — the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), M.G.L. c.118E, and other applicable laws and waivers to provide and pay for medical services to eligible members.

**Medicare** — a federally administered health insurance program for persons eligible under the Health Insurance for the Aged Act, Title XVIII of the Social Security Act (42 U.S.C. 1395-1395pp).

**Member** — a person determined by the MassHealth agency to be eligible for MassHealth.

**Nonstandard Size (Width or Length)** — a shoe size made on a standard last pattern, but which is not part of a manufacturer’s regular inventory.

**Nursing Facility (NF)** — an institution or distinct part of an institution licensed and certified for participation in Medicaid and Medicare by the Massachusetts Department of Public Health that is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured people, people with disabilities, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services that meets the requirements of the Social Security Act, §§ 1919 (a), (b), (c) and (d).

**Nurse Practitioner** — a registered nurse who has successfully completed a formal education program for nurse practitioners as required by the Massachusetts Board of Registration of Nursing (the Board), who is in good standing with the Board, and who is responsible for oversight of the member’s health care. A nurse practitioner who prescribes medication must be certified by the federal Drug Enforcement Agency (DEA).

**Off-the-shelf** — A prefabricated device or product that requires minimal self-adjustment as defined at 42 CFR 414.402 for appropriate use, *i.e.*, does not require the services of an ABC- or BOC-certified orthotist or an individual who has equivalent specialized training to adjust the device.

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Off-the-shelf Shoe — a shoe that is made on a standard last and is a regular part of a manufacturer's or provider's inventory.

Orthopedic Shoes — shoes that are specially constructed to aid in the correction of a deformity of the musculoskeletal structure of the foot and to preserve or restore the function of the musculoskeletal system of the foot.

Orthosis — a device that is:

- (1) used to support, align, correct, or prevent deformities of the body, which may be used to eliminate, control, or assist motion at a joint or body part; and
- (2) appropriate for use in the member's home or any setting in which normal life activities take place in the community.

Orthotic Assistant — an individual educated and trained to participate in comprehensive orthotic care while under the supervision of an ABC- or BOC-certified orthotist. An orthotic assistant may perform orthotic procedures and related tasks in the management of members, including fabricating repairs and maintaining orthotic devices to provide maximum fit and function.

Orthotic Services — the provision, purchase, customization, fitting, repair, replacement, or adjustment of an orthosis, orthotic supply, device, or component part, or other activity performed in accordance with 130 CMR 442.000.

Orthotic Supplies — products that are:

- (1) fabricated primarily and customarily to fulfill a medical or surgical need;
- (2) used in conjunction with an orthosis or orthotic equipment;
- (3) generally not useful in the absence of an orthosis; and
- (4) nonreusable and disposable.

Orthotics — products that are fabricated primarily and customarily to fulfill a medical or surgical need, and are generally not useful in the absence of illness, injury or disability. Pedorthic Services are a subset of Orthotics.

Orthotics Fitter — an individual who is educated and trained in the provision of certain prefabricated orthoses, including patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

Orthotics and Prosthetics Payment and Coverage Guidelines Tool — MassHealth web-based application that contains orthotics and prosthetics service descriptions for products, services, applicable modifiers, place-of-service codes, prior authorization requirements, individual consideration requirements, service limits, markup information, and links to other applicable information, such as MassHealth pricing information and additional or updated guidance issued by the MassHealth agency or its designee. The *Orthotics Manual, Subchapter 6* directs providers to the Orthotics and Prosthetics Payment and Coverage Guidelines Tool.

Orthotics Provider – an organization or individual that has enrolled with MassHealth and has signed a provider contract with the MassHealth agency who meets all applicable requirements of 130 CMR 442.404 and 450.000: *Administrative and Billing Regulations*. Orthotics providers may include providers also enrolled as MassHealth participating durable medical equipment (DME) and supplies providers, oxygen and respiratory therapy equipment and supplies (OXY) providers, or prosthetic services providers, who meet all program-specific requirements.

Orthotist — ~~a~~An individual who is noncertified or ABC- or BOC-certified and is specifically educated and trained to manage comprehensive orthotic care, including patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

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Pedorthic Service — a subset of orthotic services involving the design, manufacture, modification, and fitting of orthopedic shoes, or the fitting of therapeutic shoes for diabetics, including foot orthoses, prosthetic fillers, and orthotic or pedorthic appliances for use from the ankle and below, for the prevention or amelioration of painful and/or disabling conditions of the foot and ankle, and as provided in accordance with 130 CMR 442.000.

Pedorthist — an individual who is noncertified or ABC- or BOC-certified, and is specifically trained and educated to manage comprehensive pedorthic care, including patient assessment, custom-molding, formulation of a treatment plan, implementation of a treatment plan, follow-up and practice management.

Physician Assistant — a mid-level medical practitioner who works under the supervision of a licensed physician (MD) or osteopathic physician (DO) and who is licensed to practice as a physician assistant by the Massachusetts Board of Registration of Physician Assistants or by the licensing agency of another state, and provides health care services to the member.

Prescribing Provider — a physician, doctor of osteopathy (DO), nurse practitioner, physician assistant, or podiatrist who prescribes and writes the prescription for all orthotics and orthotic services.

Pricing, Data Analysis, and Coding (PDAC) — a CMS contractor that evaluates and processes coding verification applications from manufacturers for Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) for Medicare purposes. The PDAC also establishes, maintains and updates all coding verification decisions on the PDAC Product Classification List that is available on the Durable Medical Equipment Coding System (DMECS), which is an official source for Medicare DMEPOS product code verification and HCPCS service code assignment, and also provides coding guidance on the appropriate HCPCS service codes for DMEPOS suppliers to use when submitting DMEPOS claims to Medicare, including for orthotics.

Proof of Delivery (POD) — documentation, such as a delivery slip, that indicates that the orthotics provider delivered, or had shipped, to a specified MassHealth member, the orthotics that were intended for that member, and that the member received the orthotics.

Prior Authorization (PA) Request — a request submitted by the orthotics provider, to the MassHealth agency to determine medical necessity in accordance with 130 CMR 442.412, 450.204: *Medical Necessity*, and 450.303: *Prior Authorization*.

Service Facility — an orthotics provider's place of business (excludes a member's place of residence), where MassHealth members can obtain all orthotic services, including those involving fitting, adjustment, repair, and replacement of orthoses.

Split-size Charge — an additional charge for dispensing an off-the-shelf, medical-grade pair of orthopedic shoes, where one shoe in the pair is a different size or width than the other shoe in the pair.

Therapeutic Shoes for Diabetics — therapeutic footwear prescribed by the prescribing provider to prevent or alleviate painful or disabling conditions associated with diabetes by minimizing pressure on the foot.



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#### 442.403: Eligible Members

- (A) (1) MassHealth Members. The MassHealth agency covers orthotics provided to eligible MassHealth members, subject to the restrictions and limitations described in 130 CMR 442.000 and 450.000: Administrative and Billing Regulations. 130 CMR 450.105: *Coverage Types* specifically states, for each coverage type, that specifies which services are covered and which members are eligible to receive those services.
- (2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, *see* 130 CMR 450.106: *Emergency Aid to the Elderly, Disabled and Children Program*.
- (B) For information on verifying MassHealth member eligibility and coverage type, *see* 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

#### 442.404: Provider Eligibility

- (A) Provider Participation Requirements. Payment for services described in 130 CMR 442.000, is ~~only made to orthotics~~ providers who, as of the date of service, are participating in MassHealth as an orthotics provider; to providers also enrolled as MassHealth participating DME providers; OXY providers, or prosthetic services providers and who meet all program-specific requirements. Applicants must meet the requirements in 130 CMR 450.000: Administrative and Billing Regulations as well as the requirements in 130 CMR 442.000. Participating orthotics providers must continue to meet provider eligibility participation requirements throughout the period of their provider contract with the MassHealth agency or are a MassHealth prosthetics provider that has been assigned an orthotics specialty in accordance with 130 CMR 442.404(C).
- (B) General Qualifications. To qualify as a MassHealth orthotics provider, all applicants and providers must enter into a provider contract or agreement with MassHealth and
- (1) have a service facility that:
    - (a) is open a minimum of 30 hours per week;
    - (b) is staffed with an employee during posted business hours;
    - (c) is available to members during regular, posted business hours;
    - (d) is physically accessible to members with disabilities, and complies with all ADA guidelines;
    - (e) has clear access and space for individualized ordering, returns, repair, and storing of business records;
    - (f) has the space and capability for evaluating/assessing, repairing, modifying, adjusting and customizing products to meet members' needs;
    - (g) the provider can demonstrate their ability to fill orders, fabricate, or fit items from their own inventory or by direct purchase of items necessary to fill the order.
    - (h) has a sign visible from outside the service facility identifying the business name and hours that the service facility is open. If the provider's place of business is located within a building complex, the sign must be visible with the business name both at the main entrance of the building and the location where the service facility is located. The hours must be posted within the business complex where the service facility is located;
    - (i) has a primary business telephone number listed in the name of the business with a local toll-free telephone number that is answered by customer service staff during



business hours, and that has TTY transmission and reception capability. During business hours, this number cannot exclusively be a pager, answering service, voice message system, or cell phone; and

(j) maintains a 24-hour voice message system and/or answering service.

(2) obtain separate approval from the MassHealth agency or its designee and a separate provider number for each service facility operated by the provider;

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- (3) ~~primarily~~ engage in the business of providing orthotics, or orthotic repair services to the public, ~~except for specialty providers described in 130 CMR 442.404(C), (a MassHealth prosthetics provider that has been assigned an orthotics specialty);~~
- (4) participate in the Medicare program as a provider;
- (5) have a Medicare provider number for each business and service facility and location for which it is applying to participate or participating in MassHealth;
- (6) be accredited by the American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC), or the Board of Certification/Accreditation International (BOC) as a comprehensive orthotics facility, and display such accreditations at service facility locations;
- (7) for each service facility, maintain fulltime coverage by an ABC- or BOC-certified orthotist or orthotists responsible for overall patient care and for providing or supervising the non-certified orthotists for the provision of comprehensive orthotic services at that service facility. A noncertified orthotist must be employed by the MassHealth-enrolled Orthotics provider;
- (8) ensure that any professional staff from the disciplines listed in 130 CMR 442.404(B)(8)(a) through (d), who provide orthotic services to members meet the requirements set forth in 130 CMR 442.404(B)(8)(a) through (d), for their respective disciplines, and that the services provided are within their scope of practice and training.
  - (a) An orthotics fitter must be ABC- or BOC-certified or work under the supervision of an ABC or BOC-certified orthotist, and be employed by the MassHealth Orthotics provider.
  - (b) A fitter of therapeutic shoes for diabetics must be ABC- or BOC-certified or work under the supervision of an ABC- or BOC-certified orthotist or ABC- or BOC-certified pedorthist, and be employed by the MassHealth Orthotics provider.
  - (c) An Orthotic assistant must be ABC- or BOC-certified or work under the supervision of an ABC- or BOC-certified orthotist, and be employed by the MassHealth Orthotics provider.
  - (d) A pedorthist may be ABC- or BOC-certified or may be noncertified. A non-certified pedorthist must work under the supervision of an ABC- or BOC-certified orthotist or ABC- or BOC-certified pedorthist. All pedorthists must be employed by the MassHealth-enrolled ~~o~~Orthotics provider.
- (9) meet all applicable federal, state, and local requirements, including requirements for certifications and registrations;
- (10) at the time of application and recredentialing, or any other time as requested by the MassHealth agency or its designee, and provide all required documentation specified in 130 CMR 450.000: *Administrative and Billing Regulations* and 450.215: *Provider Eligibility: Notification of Potential Changes in Eligibility*, including:
  - (a) all current liability insurance policies;
  - (b) the property lease agreement(s) for each service facility, or a copy of the most recent property tax bill if applicant owns the business site;
  - (c) all current signed employee professional credentials, as applicable;
  - (d) the current facility ABC or BOC accreditation letter; and
  - (e) the purchase and sale agreement if the applicant or orthotics provider has recently purchased the company for which they are applying to become a MassHealth provider;
- (11) provide, or make available upon request, a copy of written policies and procedures, including the customer service protocol, customer complaint tracking and resolution protocol, and staff training;
- (12) conduct Criminal Offender Record Information (CORI) checks on employees and

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subcontractors in accordance with procedures outlined in EOHHS CORI regulations at 101 CMR 15.00: *Criminal Offender Record Checks*, and conducting applicable Office of Inspector General (OIG) verifications on all personnel;

(13) not accept prescriptions from any prescribing provider who has a financial interest in the orthotics provider or any prescribing provider who is employed by an entity that has a financial interest in the orthotics provider;

(14) cooperate with the MassHealth agency or its designee during the application and recredentialing process and record reviews, including agreeing to periodic inspections to ensure compliance with 130 CMR 442.000 and applicable state and federal laws and regulations;

(15) establish, maintain, and comply with written policies and procedures in accordance with 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*; and

(16) agree to participate in any orthotic provider orientation or any other training required by EOHHS.

~~(C) Providers Assigned Orthotics Specialty. Applicants or providers whose primary business is not orthotics or orthotic repair services for the public may qualify to provide orthotic services if the following conditions are met:~~

~~(1) the applicant or provider is enrolled as a MassHealth provider of prosthetic services in accordance with 130 CMR 428.000: *Prosthetic Services*;~~

~~(2) the applicant or provider meets all other conditions under 130 CMR 442.404 to provide orthotic services; and~~

~~(3) MassHealth has assigned a specialty of orthotics to the applicant's or provider's existing provider number for prosthetic services.~~

~~(CD)~~ In-state. To participate in MassHealth as an in-state orthotics provider, the applicant or provider of orthotics must have a service facility in Massachusetts that meets the criteria described in 130 CMR 442.404 (B), and must meet all other criteria described in 130 CMR 442.404.

~~(DE)~~ Out of state. To participate in MassHealth as an out of state orthotics provider, an applicant or provider of orthotics must meet all of the following conditions:

(1) the provider participates in the Medicare program, and participates in the medical assistance program of the state in which the provider primarily conducts business;

(2) the provider meets all applicable requirements under 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, and 42 CFR 431.52; and

(3) The MassHealth agency or its designee has determined that the out-of-state provider provides orthotics that meets a MassHealth-identified agency need.

#### 442.405: Provider Responsibilities

In addition to meeting all other provider requirements set forth in 130 CMR 442.000 and 130 CMR 450.000: *Administrative and Billing Regulations*, the provider of orthotics must:

(A) accept rates of payment established by the Executive Office of Health and Human Services as set forth in 101 CMR 334.00: *Prostheses, Prosthetic Devices and Orthotic Devices* for all orthotic services provided to MassHealth members, unless otherwise determined by the MassHealth agency or its designee through a selective contracting, preferred provider, or other process;